CITATIONS

490-678—72——1

Statutes—Continued

In the Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-666

USV PHARMACEUTICAL CORPORATION, PETITIONER

v.

ELLIOT L. RICHARDSON, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, AND CHARLES C. EDWARDS, COMMISSIONER OF FOOD AND DRUGS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

MEMORANDUM FOR THE RESPONDENTS

This petition for a writ of certiorari is the most recent in a series of petitions filed both by the government and by drug manufacturers concerning the interpretation of, and the procedures to be followed under, the drug effectiveness provisions of the 1962 Amendments to the Federal Food, Drug, and Cosmetic Act of 1938 (76 Stat. 780–796).[1] Those amendments sup-

[1] Other petitions are *Elliot L. Richardson, et al.* v. *Hynson, Westcott and Dunning, Incorporated*, No. 72-394; *Hynson, Westcott & Dunning, Incorporated* v. *Elliot L. Richardson, et*

plemented the basic Act's requirement that drugs available to the public be safe by adding the further requirement that they be effective for their intended uses. See Sections 505(a) and 201(p)(1) of the Act (21 U.S.C. 355(a) and 321(p)(1)). The Act now prohibits the interstate shipment of any "new drug" unless there is a new drug application ("NDA") approved by the Secretary of Health, Education, and Welfare [2] effective with respect to such drug.[3]

Congress also provided in Section 107(c)(4) of the 1962 amendments a "grandfather" exemption from the new effectiveness requirements. It made the exemption available to a drug which, on the day prior

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al., No. 72–414 (cross-petition); *CIBA Corporation* v. *Elliot L. Richardson, et al.*, No. 72–528; and *Elliot L. Richardson, et al.* v. *Bentex Pharmaceuticals, Inc., et al.*, No. 72–555.

[2] Under both the basic 1938 Act and the Act as amended in 1962, the Secretary has delegated his authority to the Commissioner of the Food and Drug Administration ("FDA").

[3] Congress altered the manner in which NDA's become effective. Under the basic 1938 Act, an NDA automatically became effective sixty days after filing (or one hundred and eighty days, if postponed by FDA) unless in that time FDA issued an order refusing to permit the application to become effective. See 52 Stat. 1052. As amended in 1962, the Act now requires affirmative approval of FDA before an NDA may become effective. See Sections 505 (b), (c) and (d) of the Act (21 U.S.C. 355 (b), (c) and (d)).

At the same time, Congress declared that "[a]n application filed pursuant to section 505(b) of the basic Act which was 'effective' within the meaning of that Act on the day immediately preceding the enactment date shall be deemed, as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act." P.L. 87–781, Section 107(c)(2), 76 Stat. 788, note following 21 U.S.C. 321 (1970 ed.).

to enactment of the amendments (October 9, 1962), (1) was commercially sold or used in the United States, (2) was not a "new drug" as defined by Section 201(p) of the basic 1938 Act, and (3) was not covered by an effective application under Section 505 of that Act.[4] This case involves the interpretation of this "grandfather" exemption.

1. Petitioner sells a line of citrus bioflavonoid drugs.[5] In 1956 and 1957 it had filed with FDA three NDA's covering seven of these drugs. In accordance with the terms of Section 505(c) of the 1938 Act (52 Stat. 1052), these NDA's automatically became effective after sixty days, FDA having issued no order refusing to permit them to become effective. USV also marketed two other drugs prior to 1962, similar in formula and labeling to the original seven, for which it had never filed an NDA (Pet. App. 2a, 6a). Such copies of earlier drugs are known as "me-too" drugs.

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[4] Section 107(c)(4) reads: "In the case of any drug which, on the first day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day." P.L. 87-781, Section 107(c)(4), 76 Stat. 789, note following 21 U.S.C. 321 (1970 ed.).

Sections 201 and 505 of the basic 1938 Act are found at 52 Stat. 1041-1042, 1052-1053.

[5] USV asserts that its citrus bioflavonoids are effective in the control of abnormal capillary permeability and fragility (Pet. 3).

In 1968, following reports by the National Academy of Science-National Research Council finding bioflavonoids to be ineffective (Pet. App. 39a–41a), FDA began proceedings under Section 505(e) of the amended Act (21 U.S.C. 355(e)) to withdraw approval of the NDA's for USV's bioflavonoids on the ground of ineffectiveness (Pet. App. 41a).[6] USV then sued in the district court for a declaratory judgment that its drugs are entitled to the exemption provided in Section 107(c)(4).

The district court ruled that it, and not FDA, had jurisdiction to decide the exemption question (Pet. App. 14a). It then held that all nine of the drugs were exempt: the "me-too" drugs because they were never covered by effective NDA's; the other seven drugs because USV had withdrawn their NDA's prior to October 9, 1962 (Pet. App. 14a–15a).[7] On the government's appeal the court of appeals, while agreeing that

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[6] The administrative proceedings culminated in an order issued October 15, 1970, in which the Commissioner withdrew approval of USV's NDA's for lack of substantial evidence of effectiveness (Pet. App. 46a). On review, the United States Court of Appeals for the District of Columbia Circuit reversed the Commissioner for failure to meet the requirements of administrative due process. *USV Pharmaceutical Corporation* v. *Secretary of Health, Education & Welfare and Commissioner of Food & Drugs*, C.A.D.C., No. 24,900 (August 12, 1972) (Pet. App. 36a–49a). The government has decided not to seek review of that decision. That decision does not, however, moot the issues in the present case, since FDA's withdrawal proceedings are continuing on remand.

[7] The district court found that USV's drugs were commercially used and sold in the United States on October 9, 1962. It also found that on that date all of the drugs were generally recognized as safe and hence were not new drugs as that term was defined in Section 201(p) of the basic Act then in force (Pet. App. 14a–15a).

the district court alone had jurisdiction,[*] reversed on the merits and held that none of the drugs were entitled to the exemption (Pet. App. 1a–10a). As to the seven drugs for which NDA's had been filed, the court stated that USV was without authority to withdraw an NDA once it was effective. Therefore, even though the drugs were generally recognized as safe on October 9, 1962, they nevertheless were "covered by an effective application" within the meaning of Section 107(c)(4)(C) and were thus not exempt from the drug effectiveness requirements of the 1962 amendments (Pet. App. 4a–6a). As to the two me-too drugs, the court held that, even if it be assumed that the me-toos of other manufacturers competing with USV's bioflavonoids would be exempt, USV's me-toos were not exempt because the NDA's covering its pioneer drugs, which are personal to USV, covered all of its products similar in formula and labeling (Pet. App. 6a–10a).

2. USV's petition for a writ of certiorari presents questions concerning the applicability of Section 107 (c)(4)'s exemption from the effectiveness requirements of the Act. While we do not agree with petitioner's formulation of the questions, we believe that, in light of the congressional purpose to protect the public from ineffective drugs, the interpretation of the grandfather exemption presents important issues which should be considered on this record. These issues are

[*] The court on this point cited its opinion in *Bentex Pharmaceuticals, Inc.* v. *Richardson*, 463 F.2d 363 (C.A. 4) (Pet. App. 20a–35a). The government has filed a petition for a writ of certiorari in that case: *Elliot L. Richardson, et al.* v. *Bentex Pharmaceuticals, Inc. et al.*, No. 72–555.

(1) whether a drug for which an NDA was issued prior to 1962 and never suspended by governmental action is "covered by an effective [NDA]" and therefore not exempted, and (2) whether me-too copies of such drugs are covered by the NDA of the pioneer drugs for purposes of Section 107(c)(4). These questions are important, because there are many NDA drugs and me-too drugs for which manufacturers can make the same claims to exemption that USV makes here. We believe that, in its present posture, this case fairly presents these issues and that their resolution by this Court is important to administration of the Act. Thus we agree that the Court should grant the petition for a writ of certiorari, although, for the reasons briefly stated below, we believe that none of USV's drugs is entitled to exemption.[9]

A. Petitioner's first contention is that, because its drugs were found by the courts below to have been

[9] We note that the court of appeals, on the strength of its opinion in *Bentex*, *supra*, also held that the courts alone have jurisdiction to decide whether a drug is entitled to the exemption (Pet. App. 2a). We have filed a petition for review of the *Bentex* decision (*Elliot L. Richardson, et al.* v. *Bentex Pharmaceuticals, Inc., et al.*, No. 72–555) in which we not only contend that FDA does have jurisdiction to decide whether a drug is a new drug, but also indicate that where technical questions relating to agency expertise are involved, the primary jurisdiction doctrine may oblige courts to defer to FDA. Pet. No. 72–555, *supra*, at p. 18, n. 15. We adhere to that view. But since, after a full district court trial, there are now no disputed issues of fact in the present case, and since there remain only important and generally applicable issues of statutory construction on which the agency's views are being presented by the government, we believe it would be proper for this Court to decide the issues presented by USV's petition.

generally recognized as safe prior to October 9, 1962, and because FDA was found to have acquiesced in USV's cessation of adherence to the labeling and data submission procedures required for NDA products, the drugs had ceased to be new drugs under the basic Act and were no longer "covered by an effective application" as of that date (Pet. 14–18). The court of appeals rejected this argument on the grounds that nothing in the statute gave a manufacturer the right to withdraw an effective NDA, and that to treat NDA drugs as new drugs exempt from the Act because they are generally recognized as safe would make meaningless surplusage of Section 107(c)(4)'s further requirement that, prior to the enactment date, the product not be "covered by an effective application."[10]

The court of appeals' construction accords with the congressional purpose as well as with the statutory language. Section 107(c)(4) limits exemptions from the efficacy requirement to drugs which, as of October 9, 1962, were not "new drugs" within the meaning of Section 201(p) of the 1938 Act (Section 107(c)(4)(B)) *and* were not covered by an effective NDA (Section 107(c)(4)(C)). The requirements are conjunctive, not alternative. Thus clause (C) presupposes that the drugs to which it applies were, in accord with clause (B), not new drugs. The argument

[10] The same contention was also rejected by the Fourth Circuit in *Hynson, Westcott & Dunning, Inc.* v. *Richardson*, 461 F. 2d 215, and Hynson has raised the issue before this Court in its cross-petition for a writ of certiorari (No. 72–414). The government has acquiesced in the granting of Hynson's cross-petition in No. 72–414.

that general recognition of safety, and thus the loss of new drug status, by 1962 entitled a drug to a Section 107(c)(4) exemption would render clause (C) of the exemption section meaningless and redundant. Had Congress intended to adopt USV's view, it would have provided exemption for any drug which "was not a new drug" under the basic Act, "and *therefore* was not covered by an effective application."

Nor is USV's argument of greater merit when combined with evidence that USV, with the acquiescence of FDA, ceased to comply with certain procedures required of effective NDA's. As the court of appeals rightly observed, nothing in the basic 1938 Act authorizes a manufacturer to withdraw an effective NDA, either directly or indirectly. Indeed, prior to the 1962 amendments, FDA itself had no authority to withdraw an NDA. It could only suspend the effectiveness of an application, and the 1938 Act carefully prescribed both the substantive grounds for suspension and the procedural rights which the government had to afford the party affected. See 52 Stat. 1053. In view of the specificity with which Congress delimited the powers of FDA to suspend the effectiveness of an NDA, petitioner's admittedly inferential attempt to add to the statutory scheme a new means for rendering NDA's ineffective (Pet. 17) is without foundation.

B. Petitioner's second contention is that the court of appeals erred in holding that USV's me-too drugs were not exempt under Section 107(c)(4), while indicating that such me-too drugs, if produced by another manufacturer, would be exempt (Pet. 18–22). The

court of appeals assumed, *arguendo*, that as a general rule me-too drugs are entitled to exemption. This conclusion was based on its view that, under Section 505, NDA's are personal to the manufacturer and specific to the drug covered, a view reinforced by FDA's pre-1962 practice. However, the court held that USV's me-too drugs, being similar to other USV products covered by effective NDA's, are not exempt because the personal character of the NDA extends its coverage to all similar products of the manufacturer (Pet. App. 8a–10a).

We believe that the court of appeals reached the right result, but for the wrong reason. The purpose of Congress in passing the 1962 drug effectiveness amendments was to insure that drugs marketed to the American public are effective as well as safe. Thus, even though a drug was covered by an NDA issued prior to October 10, 1962, the amendments required that it meet the new standard of effectiveness. This congressional intent to protect the public against ineffective drugs would be frustrated in substantial measure if the large body of me-too drugs, similar in composition and labeling to NDA drugs, could be sold to the public regardless of their effectiveness.[11]

It is in light of this important statutory purpose that the coverage language of Section 107(c)(4)

[11] Moreover, such a result would create competitive inequities among drug manufacturers by requiring the holder of an NDA to show the effectiveness of its product while leaving the manufacturer of the me-too free to market an imitation of the drug even if it is ineffective. Such an unfair result should not lightly be attributed to Congress.

should be read. Section 107(c)(4) provides exemption for a drug "not covered by an effective application under Section 505" of the basic 1938 Act. It is our position that me-too drugs are "covered" by the effective NDA of the pioneer, whether the me-toos are made by the manufacturer of the pioneer drug or by a competitor, because the me-toos are basically the same pharmacologically as the NDA drugs, and because issuance of the pioneer's NDA normally provided the predicate for lawful marketing of the copies.

Although both the petitioner and the court of appeals maintain that NDA's were "personal" to each manufacturer of the drug under Section 505 of the 1938 Act, the statute's provisions suggested a broader, generic coverage for NDA's. Section 505(a) provided that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug." 52 Stat. 1052. And Section 505(b), in its list of items of information to be supplied to FDA, contained items which looked to the safety of the drug as a generic article, in addition to "personal" information on the methods, facilities and controls which a particular company would use in its manufacture, processing and packaging.[12] The generic factors applied to a drug whether it was made by USV or by a competitor; in other words, under the 1938 Act, either citrus bioflavonoids

[12] Compare Section 505(b)(1)–(3) with Section 505(b)(4). 52 Stat. 1052.

of a particular pharmacological composition and intended use were safe or they were not safe. When FDA permitted the original NDA's to become effective, therefore, the NDA's presumptively established (subject to possible subsequent re-evaluation and suspension) that the formulation and use covered was marketable as a general class of product.

It is true, as petitioner and the court of appeals point out (Pet. 19–21; Pet. App. 8a–9a), that respondents' present position represents a change from that taken for many years prior to 1962. Enactment of the 1962 amendments, however, necessitated reconsideration of the distinction formerly made by FDA between the personal and generic attributes of an NDA. In order to carry out the statutory purpose of insuring the effectiveness of drugs, FDA properly recognized that NDA's could be treated as generic in matters susceptible of such treatment. An NDA thus could rightly be said, as to generic matters (as distinguished from particularized matters relating to conditions of production, etc.), to be "effective" under Section 505 not only for the particular drugs but for all others similar in composition and use. Accordingly, USV's effective NDA's covered not only USV's me-too drugs, but any competitor's me-toos as well.[13]

[13] If, however, the Court should reject respondents' interpretation of the exemption and read NDA's as being personal to the manufacturer and the drug, then we agree with petitioner that the distinction drawn by the court of appeals between USV's me-toos and those of its competitors is discriminatory and not supportable.

3. USV's petition appears to be the last in the current group of petitions raising questions involving the interpretation and administration of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act. All told, four decisions of the courts of appeals have generated five petitions for certiorari stating nine questions for resolution by this Court. The government has filed two of these petitions (*Hynson*, No. 72-394; and *Bentex*, No. 72-555) and has recommended the granting of certiorari in the other three (*Hynson* (cross-petition), No. 72-414; *CIBA*, No. 72-528; and the instant case, *USV*, No. 72-666).

While the Court may, if it decides to grant certiorari in any or all of the cases, wish to hear them in the normal manner, we believe that the degree of interrelation among the cases and the extent to which they present overlapping issues warrant consideration of an alternative approach designed to avoid unnecessary duplication of arguments and to focus the issues for resolution by the Court. Accordingly, we respectfully offer to the Court and the other parties the following suggestions for the briefing and argument of these cases.

In our view, the nine questions presented by the pending petitions can fairly be grouped into three general questions, which are logically susceptible of separate briefing and argument: (a) whether particular categories of drug products are immune from the efficacy requirements of the 1962 amendments; (b) whether the resolution of certain factual issues inci-

dent to the determination of the lawfulness of marketing of a drug is exclusively within the jurisdiction of the courts; and (c) whether FDA may, in certain circumstances, properly decline to hold an evidentiary hearing under Section 505(e).

(a) *The "immunity" issues.* Questions 3 and 4 raised by the cross-petition in *Hynson* (No. 72–414) and question 1 presented by USV's petition in the instant case involve the interpretation of Section 107(c)(4) and the contention that drugs for which NDA's became effective between 1938 and 1962 are immune under that provision from the efficacy requirements of the 1962 amendments if they were generally recognized as safe by 1962. Question 2 presented by USV's petition in the instant case raises the question whether Section 107(c)(4) confers immunity from the efficacy requirements of the 1962 amendments upon ineffective me-too drugs when the NDA of the pioneer of which they are copies is withdrawn because of the absence of substantial evidence of the drug's effectiveness (this issue is also inherent in *Bentex,* although not necessary to the decision of the court of appeals because of its disposition of the jurisdictional issue). Question 2 presented by the cross-petition in *Hynson, supra,* involves the contention that a drug that is today "generally recognized" as safe and effective is immune from the requirement that it adduce "substantial evidence" of effectiveness.

We propose that Hynson and USV file opening briefs addressed to these "immunity" issues, and that the government file a brief in response on this group of

issues.[14] We suggest that the Court grant one and a half hours of oral argument on these issues.

(b) *The jurisdictional issues.* The government's petition in *Bentex* (No. 72–555) raises the issue whether the FDA had jurisdiction to determine initially whether a product is a "new drug" which must be administratively approved as safe and effective before it may be sold in commerce. The manufacturer's petition in *CIBA* (No. 72–528) raises the issue whether the federal district courts have exclusive jurisdiction to adjudicate the "new drug" status of a product, the manufacturer having failed to raise the issue in administrative proceedings for withdrawal of the drug's NDA and on direct judicial review of such proceedings. Both of these questions, together with question 1 presented by the cross-petition in *Hynson, supra,* raise fundamental issues concerning the jurisdiction of court and agency to resolve factual contentions upon which "immunity" claims may turn.

With respect to these jurisdictional issues, we propose that the government file an opening brief and that Bentex, CIBA, and Hynson file briefs in re-

[14] Since "immunity" claims underlie the declaratory judgment actions brought by the *Bentex* respondents and by CIBA, those parties may wish to brief the "immunity" issues also, and the government would have no objection to their doing so.

sponse. We suggest that the Court grant one hour of oral argument on these issues.

(c) *The hearing issue.* The government's petition in *Hynson* (No. 72–394) challenges the order of the court of appeals requiring the grant of an evidentiary hearing to Hynson, in connection with the withdrawal of an NDA under Section 505(e), in the absence of submission by Hynson of "substantial evidence" of effectiveness, consisting of adequate and well-controlled clinical investigations, in support of its request for a hearing. We propose that this case be handled in the normal manner.

The foregoing is not intended to suggest that the three general topics delineated above are unrelated to one another. On the contrary, we believe they are interrelated, but that the precise nature of the relationship is dependent in part upon the manner in which the various questions presented by these cases are answered. On balance, however, we believe that the topical division suggested herein may provide a useful framework for analysis and resolution of the complex and interrelated issues raised by the pending petitions.

4. Copies of this Memorandum are also being served upon Bentex, CIBA, and Hynson so that they may have an opportunity to respond to our suggestions concerning the procedure for briefing and argument of these cases.

CONCLUSION

For the reasons stated, the present petition for a writ of certiorari should be granted.

Respectfully submitted.

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DECEMBER 1972.

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AMICUS CURIAE BRIEF

No. 72-394

IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

ELLIOT RICHARDSON, Secretary of Health, Education and Welfare, and CHARLES C. EDWARDS, Commissioner of Food and Drugs,

Petitioners,

v.

HYNSON, WESTCOTT AND DUNNING, INCORPORATED

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE IN SUPPORT OF PETITION OF THE UNITED STATES FOR A WRIT OF CERTIORARI AND BRIEF AS AMICI CURIAE IN SUPPORT OF PETITION OF THE UNITED STATES FOR A WRIT OF CERTIORARI ON BEHALF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION AND NATIONAL COUNCIL OF SENIOR CITIZENS

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INDEX

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Petitioners,

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MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE IN SUPPORT OF PETITION OF THE UNITED STATES FOR A WRIT OF CERTIORARI ON BEHALF OF THE AMERICAN PUBLIC HEALTH ASSOCIATION AND NATIONAL COUNCIL OF SENIOR CITIZENS

The American Public Health Association and National Council of Senior Citizens hereby respectfully move for leave to file the attached brief *amici curiae* in support of the petition of the United States for a writ of certiorari in this case. The consent of the United States has been obtained and has been filed with the Clerk of this Court. The consent of the respondent was requested but denied.

The immediate interest of the American Public Health Association and National Council of Senior Citizens in this case arises from the fact that they have been successful plaintiffs in a recent court action against the Food and Drug Administration. The Food, Drug and Cosmetic Act requires the Food and Drug Administration to remove drugs marketed between 1938 and 1962 from the market if the FDA find that they lacked substantial evidence of effectiveness. The FDA has still not completed its review of most of those drugs 10 years later and therefore hundreds of drugs, which the National Academy of Sciences and the FDA itself have found to be ineffective, are still being sold. The district court, on October 11, 1972, directed the FDA to proceed "expeditiously" to withdraw drugs found to be ineffective and established specific deadlines for implementation of the determination. *American Public Health Ass'n* v. *Veneman*, No. 1847-70, District Court for the District of Columbia.[1]

As is described more fully in the attached brief in support of the petition of the United States for a writ of certiorari, the decision of the court of appeals in this case may seriously interfere with compliance by the Food and Drug Administration with the order of the district court in *American Public Health Ass'n* v. *Veneman*. The decision of the court of appeals will impose substantial additional burdens on the FDA which has already failed to enforce the 1962 amendments to the Food, Drug and Cosmetic Act. The American Public Health Association and National Council of Senior Citizens seek to file a brief supporting the petition of the United States to protect the order of the district court and, more broadly, the interest of the public in the enforcement of this extremely important statute.

The involvement of the American Public Health Association and National Council of Senior Citizens in *Ameri-*

[1] The opinion and order of the district court are included in the appendix below.

can *Public Health Ass'n* v. *Veneman* is the culmination of the long-standing concern of both organizations for protecting the public from the abuses of ineffective drugs. Formed in 1961, the National Council of Senior Citizens is a non-profit association of over 3,000 senior citizen groups from different states with a combined membership of over 3,000,000 elderly people. The purpose of the organization is to provide education and to act as a national clearinghouse on matters of interest to senior citizens. The interest of the elderly in drug effectiveness is a critical one. Of people 65 and older, over 85 percent are suffering from one or more chronic conditions and, as a result, elderly people use three times the amount of drugs as the average American citizen. This need for drugs—coupled with the fact that one out of four of the 22 million persons under the poverty line of $1,900 a year is over the age of 65—makes the problem of costly and ineffective drugs an extremely important matter for senior citizens. In view of the importance of drugs and medical care generally to the elderly, the National Council of Senior Citizens was a principal supporter of Medicare, has actively participated in drafting legislation to extend Medicare coverage to out-of-hospital drugs, has worked for consumer representation on the Joint Commission on the Accreditation of Hospitals, and joined with two other organizations in 1966 to form a drug cooperative in an effort to reduce the rising cost of drugs.

The American Public Health Association is a national professional organization whose membership of over 26,000 consists primarily of profesional public health workers, including doctors, nurses, and hospital administrators. The Association, which is 100 years old this year, was organized to provide public-health professionals with a vehicle for influencing national and local public

health policy. It publishes a monthly magazine, the *American Journal of Public Health*, consisting of papers from its membership, and a monthly newspaper, the *Nation's Health*. Concern with this country's drug problem, including drug ineffectiveness, dominated a major part of the 1972 annual meeting of the Association. As a result, several resolutions supporting broader regulation of the drug industry and increased appropriations to the Food and Drug Administration and other federal agencies charged with the responsibility of safeguarding the public's health were adopted by its members.

The filing of a brief as *amici curiae* is timely. The order of the district court in *American Publc Health Ass'n* v. *Veneman* was not issued until October 11, 1972. The plaintiffs in that case did not learn of the decision of the court of appeals in the instant case until the hearing on the order before the district judge. During that hearing, the Food and Drug Administration told the court that the decision of the court of appeals in this case would seriously interfere with, and might even completely prevent, compliance with any order in *American Public Health Ass'n* v. *Veneman* requiring the FDA to proceed expeditiously, within specified time periods, to enforce the 1962 amendments to the Food, Drug and Cosmetic Act. The American Public Health Association and National Council of Senior Citizens have subsequently moved promptly to file a brief *amici curiae* in this case.

The petition of the United States was filed on September 7, 1972, and the response of respondent was filed on October 6, 1972. However, the respondent in this case has filed its own petition for a writ of certiorari based on the same decision of the court of appeals and the response of the government is due on October 31, 1972. Since this motion and the accompanying brief are also being filed on October 31, the parties will not be prejudiced and the case will not be delayed by the granting of this motion.

CONCLUSION

For the foregoing reasons, we respectfully submit that the Motion to File Brief Amici Curiae in Support of the Petition of the United States for a Writ of Certiorari should be granted.

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1972

No. 72-394

ELLIOT RICHARDSON, Secretary of Health, Education and Welfare, and CHARLES C. EDWARDS, Commissioner of Food and Drugs,

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STATEMENT OF INTEREST OF AMICI CURIAE

The interest of the American Public Health Association and National Council of Senior Citizens is fully described in the Motion for Leave to File Brief Amici Curiae above.

REASONS FOR GRANTING THE WRIT

Congress passed in 1962 the Harris-Kefauver Amendments to the Food, Drug and Cosmetic Act, 76 Stat. 781, requiring for the first time that drugs sold to the public be shown to be effective for their intended uses. Congress deferred enforcement of the amendments for two years for drugs on the market before 1962. 76 Stat. 788-789. Thus, the Act allowed the marketing of pre-1962 drugs after 1964 only if they had been shown to be effective.

In fact, the 1962 amendments are still substantially unenforced even today. The Food and Drug Administration has found that 628 drugs are "possibly effective" but it has completed action on only 117 of these drugs. Since 102 of these drugs were finally found to be ineffective and only 15 to be effective, it is almost certain that most of the remaining 511 possibly effective drugs are lacking substantial evidence of effectiveness.[2] Similarly, the FDA has found that 197 drugs are "probably effective" and has finished administrative action on only 22. Since 14 of these drugs were found to be ineffective and only 8 to be effective, it is likely that a majority of the remaining 175 drugs will be found ineffective. While the Food and Drug Administration has not supplied *amici curiae* with exact statistics, there are hundreds of additional drugs still on the market which the FDA has found to be ineffective as to all their claimed uses or has found that they are effective for some claimed uses but have not been shown to be effective for other uses.

[2] The Food and Drug Administration has used the labels "ineffective," "possibly effective," "probably effective," and "effective" in its initial evaluations of drugs. In terms of the statute, however, there are only two categories of drugs—drugs which have been shown to be effective on the basis of substantial evidence and drugs which have not. 21 U.S.C. 355(e). Thus, drugs found to be possibly effective or probably effective, like those found to be ineffective, cannot be legally marketed under the statute.

Thus, 10 years after passage of the 1962 amendments and 8 years after Congress intended them to become effective, hundreds of ineffective drugs continue to be sold to the public.

The District Court for the District of Columbia considered this extremely important federal statute in *American Public Health Ass'n* v. *Veneman*, C.A. No. 1847-70. On August 23, 1972, the district court held that the Food and Drug Administration engaged in "intolerable procrastination" in evaluating reports made to it by the National Academy of Sciences concerning the efficacy of drugs and that hearings had been subject to "interminable delay"; that the FDA had extended the two-year grace period for enforcement of the Act "far beyond that envisioned by the statute"; and that it had "effectively stay[ed] implementation of the Congressional mandate that drugs in the marketplace be both safe and effective."

Subsequent to its opinion, the district court issued an order on October 11, 1972, establishing a time schedule for the FDA to complete enforcement of the 1962 amendments concerning pre-1962 drugs. The court ordered that its administrative review be completed within a total of four years—drugs found ineffective by the FDA within one year of the order; possibly effective drugs within the following 18 months; probably effective drugs within the following year; and drugs which were effective as to some uses and less than effective for other uses within the next 6 months. Judge Bryant retained jurisdiction and ordered that the FDA submit reports every six months describing its progress in enforcing the statute.

The decision of the Court of Appeals for the Fourth Circuit in this case greatly expands the right of drug manufacturers to obtain administrative hearings. Section 505(e) of the Food, Drug, and Cosmetic Act, 21 U.S.C. 355(e), requires drug manufacturers to demonstrate the effectiveness of drugs they market by "substantial evi-

dence." Substantial evidence is defined by Section 505 (d) of the Act, 21 U.S.C. 355(d), as "adequate and well-controlled investigations." The FDA has therefore issued regulations providing that drug manufacturers are entitled to hearings only if they produce "adequate and well-controlled clinical investigations to support the claims of effectiveness." 21 C.F.R. 130.14, as amended, 35 Fed. Reg. 7252. The court of appeals below ordered the FDA to grant respondent a hearing although the FDA had found that respondent had submitted no evidence meeting the statutory definition of "substantial evidence" and therefore no issue was properly raised for the hearing.

The hearing afforded by the court of appeals does not protect any legitimate rights of drug manufacturers. The Food, Drug and Cosmetic Act and implementing regulations define the kinds of evidence which the FDA may consider. Manufacturers have had 10 years to conduct tests meeting the statutory requirements. A drug manufacturer is of course entitled to a hearing where it presents some "substantial evidence" as defined by the statute. No purpose, however, is served by granting a hearing where the manufacturer's only evidence must, and will inevitably, be rejected by the FDA. The only effect of the decision below will therefore be to afford opportunities to drug manufacturers for further delay in removing ineffective drugs from the market.

The decision of the court of appeals may have serious effects for carrying out the district court's order in *American Public Health Ass'n* v. *Veneman* and for enforcement of the 1962 amendments. During the hearings before Judge Bryant concerning the order, the Food and Drug Administration repeatedly represented that it would be unable to comply with the deadlines in the order and would require years of additional time if it were required to afford hearings to drug manufacturers whenever evidence was submitted of effectiveness even though this

evidence did not consist of "adequate and well-controlled investigations" as required by the Act. If hearings can be obtained on the basis of such evidence, it is likely that most manufacturers will request them since they are entitled to continue selling drugs until the hearing is held and a subsequent determination is made. The FDA noted that a recent drug hearing had taken 3 months to complete. *In the Matter of SERC Tablets*, Unimed, Inc., Docket No. FDCD-111, 1969. The FDA contended that it does not have the hearing examiners, attorneys, scientists, or other resources to handle hundreds of lengthy administrative hearings expeditiously.[3]

Amici curiae do not accept the suggestion that the FDA need not comply with the district court's order if the decision of the court of appeals is not reversed. We believe that the FDA and the Executive Branch still have the duty to enforce the 1962 amendments to the Food, Drug and Cosmetic Act. If the FDA does not have the personnel to afford legally necessary procedures and still enforce the law, the FDA and the rest of the Executive Branch are legally required to seek additional funds.

Nevertheless, *amici curiae* strongly support the position of the Food and Drug Administration in this case. The decision of the Court of Appeals for the Fourth Circuit will allow manufacturers to delay even further the withdrawal of ineffective drugs from the market. It will seriously interfere with prompt enforcement of the 1962 amendments which should long ago have required the withdrawal of all ineffective drugs from the

[3] The FDA has similarly stated in its petition for a writ of certiorari in this case (p. 17, note 9) that "[m]anifestly, the agency will be unable to satisfy the thrust of that decision [in *American Public Health Ass'n* v. *Veneman*] to expedite review and appropriate withdrawal actions if it must meet the standard for granting evidentiary hearings prior to withdrawal that has been imposed by the court of appeals in the instant case."

market. It will consume manpower urgently needed by the FDA to enforce not only the 1962 amendments, but other provisions of the Food, Drug and Cosmetic Act and other statutes. We therefore submit that this case raises issues of substantial national importance involving the ability of the Food and Drug Administration to enforce important federal statutes designed to protect the public health.

CONCLUSION

For the foregoing reasons, we respectfully submit that the petition of the United States for a writ of certiorari should be granted.

BRUCE J. TERRIS
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APPENDIX A

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Civil Action No. 1847-70

[Filed Aug. 23, 1972—James F. Davey, Clerk]

AMERICAN PUBLIC HEALTH ASSOCIATION AND NATIONAL COUNCIL OF SENIOR CITIZENS,
Plaintiffs,

v.

JOHN G. VENEMAN, Acting Secretary of the Department of Health, Education and Welfare, and CHARLES EDWARDS, Commissioner of the Food and Drug Administration,
Defendants.

MEMORANDUM AND ORDER

I

Before the court are the cross-motions of the parties for summary judgment. Because of the complex nature of this case, a detailed recitation of the facts is appropriate.

In 1962, the Congress amended the Food, Drug, and Cosmetic Act of 1938 to require that all drugs on the market be proven effective for their suggested use.[1] Under 21 U.S.C. § 355(e) (1970),

> The Secretary shall, after due notice and opportunity for a hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds . . .

[1] P.L. 87-781. The pertinent amendments are codified in 21 U.S.C. §§ 355, 357 (1970 ed.).

> (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof. . . .

Section 355 relates solely to non-antibiotic drugs. Under § 357(h), antibiotic drugs may be ordered withdrawn when

> (2) the Secretary finds, on the basis of new information with respect to such drug evaluated with the information before him when the application under section 355 of this title became effective or was approved, that there is a lack of substantial evidence (as defined in section 355(d) of this title) that the drug has the effect it purports or is represented to have under such conditions of use.

The term "substantial evidence," as used in §§ 355(e) and 357(h) means

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. 21 U.S.C. § 355(d) (1970).

Under the terms of P.L. 87-781, Section 107(c)(3)(B), the effectiveness requirement did not take effect until October 10, 1964, two years after enactment of the statute. The Food and Drug Administration in 1964

promulgated regulations to require the drug manufacturers to report whether approved drugs were still being marketed in conformity with the conditions for which they had been approved and to submit scientific data in support of any claims in promotional material which departed from the approved labeling. The drug industry failed to comply, and litigation instituted in the District of Delaware by the Pharmaceutical Manufacturers Association challenging the legality of the regulation was still pending as of September 3, 1970.[2]

In 1966, Dr. James Goddard became Commissioner of FDA and began to move ahead with efficacy studies of the various drugs. In July of 1966, a contract with the National Academy of Sciences-National Research Council was signed, whereby the NAS-NRC was to review the efficacy of all drugs which had been given FDA approval from 1938 to 1962. The FDA then published orders in the Federal Register requiring the drug manufacturers to submit certain information regarding each approved drug, including references to evaluations of the effectiveness of the drug. The purpose was to permit the manufacturers the "opportunity to identify the best available evidence which they believed supported the claims made for the drug."[3] After several extensions, the manufacturers were required to submit their information by July 1, 1967.[4] NAS-NRC began submitting its first reports on October 11, 1967, and submitted the last report on April 15, 1969; there were 2,824 reports submitted, covering approximately 3,700 drugs manufactured by 237 companies.

In January, 1968, the FDA began implementation of the NAS-NRC reports. The procedure adopted has

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[2] Affidavit of Charles C. Edwards, filed September 4, 1970, p. 3.

[3] Affidavit of Charles C. Edwards, *supra*, Note 2, pp. 5-6.

[4] It should be noted that this date is nearly three years after the effective date of §§ 355 and 357.

been to evaluate each report and to release it to the public only after the FDA evaluation is completed. When the FDA completes its evaluation of an NAS-NRC report, an announcement is made in the Federal Register that the FDA has concluded that the drugs involved are "effective," "probably effective," "possibly effective," or "lack substantial evidence of effectiveness"; the first three classifications are the same as those used in the NAS-NRC reports, but the last seems to be an FDA substitution for the NAS-NRC classification "ineffective."

After announcing the classification of a drug in the Federal Register, the FDA affords the drug manufacturer a period of time to provide additional data to the FDA in every case where the drug is classified as anything other than "effective." The manufacturer is given 12 months or 6 months where the drug is listed as probably or possible effective, respectively,[5] and 30 days where the drug is classified as lacking substantial evidence of effectiveness.[6] During this time period, the manufacturer is permitted to continue marketing the drug. If, at the end of the interim period, no studies have been undertaken by the manufacturer, or if the studies do not provide substantial evidence of effectiveness, procedures are supposed to be instituted to withdraw approval of the drug pursuant to 21 U.S.C. § 355(e).[7]

When the Secretary finds that a drug lacks substantial evidence of efficacy, §§ 355(e) and 357(h) & (f) require that there be an opportunity for a hearing. 21 C.F.R. § 130.27 (1971) prescribes the procedure for withdrawal of non-antibiotic drugs. The Secretary is required

[5] See Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, 35 Fed. Reg. 11273 (1970).

[6] See, e.g., 35 Fed. Reg. 12423 (1970).

[7] See Conditions for Marketing New Drugs, *supra*, Note 5. It is unclear from the record whether this procedure has been applied to antibotics.

to notify the holder of a new drug application of an opportunity for a hearing on the proposed withdrawal, and notice must be published in the Federal Register. The manufacturer has 30 days then to avail himself of the hearing opportunity.[8] If the manufacturer fails to avail himself of the opportunity for the hearing, the FDA may enter a final order withdrawing the drug.[9] When a manufacturer desires to have a hearing, he must respond within the 30 days after notice is published, giving reasons, supported by an analysis of clinical and investigative data which he would present at the hearing in support of his opposition to withdrawal of the drug.[10] The FDA may refuse a hearing and withdraw the drug where the data presented is insufficient on its face to support a claim of effectiveness.

Though the language of 21 C.F.R. § 130.14(b) (1971) is ambiguous, it appears that a hearing, when permitted, must commence as soon as practicable. After the hearing the examiner submits tentative findings of facts and an order which becomes final if no objection is made within 20 days thereafter. The Commissioner of the FDA then issues the final order. The procedure followed in the cases of antibiotic drugs is contained in 21 C.F.R. § 146.1 (1971) and is sufficiently similar as to not require separate discussion.

II

As a preliminary matter, the question of jurisdiction is quickly resolved. The defendants contend that the matters in controversy are within the agency's discretion and are thus subject neither to mandamus nor judicial review. The court has considered both the allegations of the complaint and the merits and concludes, as will

[8] 21 C.F.R. § 130.14(a) (1971).

[9] 21 C.F.R. § 130.15 (1971).

[10] 21 C.F.R. § 130.14 (1971).

be shown later in this memorandum, that the issues presented do not deal with agency discretion and are subject to review under the Administrative Procedure Act.[11]

III

The plaintiffs' complaint challenges in several respects the manner in which the FDA is administering Sections 355 and 357.

A.

First the plaintiffs assert that the FDA practice of granting manufacturers time to bolster the record regarding a drug's effectiveness, after the FDA has publicly concluded that a drug is less than effective, is a violation of the statutory mandate. The statute states unequivocably that

> The Secretary *shall* . . . withdraw approval of any application with respect to any drug under this section if the Secretary finds . . . that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed . . . 21 U.S.C. § 355 (e) [Emphasis added].

While § 355(e) pertains only to non-antibiotic drugs, 21 C.F.R. § 146.1(g)(1) (1971) declares that

> No regulation providing for the certification of any batch [of antibiotic drugs] . . . and no existing regulation will be continued in effect unless it is established by substantial evidence that the drug will have such characteristics . . . to adequately insure safety and efficacy of use.

Thus it could not be clearer that the Secretary *must* begin the procedures to withdraw a drug when he concludes that there is no substantial evidence of efficacy. The defendants contend that the many announcements

[11] 5 U.S.C. §§ 701-706 (1970).

which have been published in the Federal Register regarding FDA conclusions about the efficacy of various drugs are not findings by the agency [12] and that the FDA is "not required by law to notice the cases [where a drug has been found less than effective] or press them to hearing immediately upon its announcement of the NAS-NRC findings and its concurrence. It has discretion in the selection of cases to notice for hearing." [13] This argument is unpersuasive in view of the clear language of the statute and regulations and the Congressional intent to rid the marketplace of ineffective drugs.[14]

B.

The plaintiffs' second claim is that once the FDA commences the procedure outlined in the statute or regulation for withdrawing a drug, it fails to adhere to those procedures. Plaintiffs assert, and the defendants do not refute it, that for many drugs the FDA has published in the Federal Register the required notice of an opportunity for a hearing and that the manufacturers have failed to avail themselves of the opportunity for

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[12] Defendants' Reply Brief, p. 2.

[13] Defendants' Memorandum in Support of Defendants' Motion to Dismiss and for Summary Judgment, p. 20.

[14] The court feels compelled to state that even if the statute and regulation did not require immediate action by the FDA to withdraw an ineffective drug, the court would grant mandamus based upon not only the statute, but also the failure of the FDA to adhere to its regulation declaring that a drug would be withdrawn at the end of a 30 day, 60 month or 12 month period. 35 Fed. Reg. 11273 (1970). See pp. 30-32 of Plaintiffs' Memorandum in Support of Motion for Summary Judgment. Furthermore, the court cannot understand the solicitude of the FDA for the drug manufacturers in giving additional time to supplement the record when in all cases the manufacturers have been on notice regarding the statute's efficacy requirement for at least four or more years. The hearing procedure provides ample opportunity for drug manufacturers to produce their scientific evidence, when they have any, in opposition to withdrawal.

the hearing within the required 30 days; nevertheless the FDA has failed to withdraw these drugs from the market. In these circumstances, the withdrawal is both required by the statute and purely a ministerial duty, and failure to withdraw constitutes agency action unlawfully withheld.

In addition, plaintiffs contend that where drug manufacturers have requested a hearing, such hearings have been a long time in coming. They cite as examples two drugs where no hearing had been scheduled at the time the plaintiffs filed their memorandum, even though the manufacturers had requested hearings one and a half years before. Indeed, this situation was commented upon unfavorably in *U. S. V. Pharmaceutical Corporation* v. *Secretary, HEW*, No. 24,900, slip op. at 14 (D.C. Cir. August 14, 1972). As the court reads 21 C.F.R. § 130.14(b), a hearing on withdrawal of a new drug application is to be scheduled as soon as practicable, and while such a provision confers some agency discretion in scheduling the hearing, interminable delay obviously is not contemplated.

C.

Plaintiffs also claim that the FDA has failed to exercise its authority to immediately suspend drugs which present an imminent hazard to the public health.[15] The invocation of this emergency procedure is a matter which is peculiarly one of judgment, and while the agency has been, perhaps, overcautious on occasion in view of the lengthy delays in removing drugs from the market, the record before the court is inadequate to support a finding of an abuse of discretion.

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[15] 21 U.S.C. § 355(e) (1970) and 21 C.F.R. § 146.1 (1971).

IV

When the final motion paper was filed in this case on December 1, 1970, less than half of the NAS-NRC report had been evaluated and published.[16] In his affidavit filed September 4, 1970, the defendant Commissioner of the FDA stated

> In summary, it is expected that all the reports will be released and FDA and Academy findings published prior to July 1, 1971.[17]

In response to the court's inquiry the defendants advised the court on February 2, 1972, that 814 reports still had not been evaluated by the FDA. Of these outstanding reports, 327 had been returned to NAS-NRC for further evaluation in early 1971 and were reported on by NAS-NRC in October, 1971; they are presently being reevaluated by the FDA. In addition, the FDA has advised that the 260 NAS-NRC reports on over-the-counter drugs will not be rated by the FDA (and hence will remain unpublished) because it has announced a new program with regard to over-the-counter drugs.[18] The plaintiffs have protested that the proposed procedures are "enormously elaborate" and will create extensive delay in applying the efficacy requirement to over-the-counter drugs. The court shares this concern, since over-the-counter drugs are purchased without medical advice in most cases, and an NAS-NRC report on over-the-counter drugs indicates that only 25% of all such drugs are effective.[19]

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[16] Defendants' Reply Brief, p. 6, indicates that 1188 out of 2771 NAS-NRC reports have been published.

[17] Affidavit of Charles C. Edwards, *supra*, Note 2, p. 12.

[18] 37 Fed. Reg. 85 (1972).

[19] Id. at 85. The type of intolerable procrastination in the FDA evaulation of NAS-NRC reports has been dramatically evidenced very recently. The FDA has just released for publication an NAS-

Because the FDA has responsibility in matters which directly and literally affect the nation's health and welfare, it is one of the most important of all Federal regulatory agencies. Its enforcement stance must be well balanced, but nevertheless effective. A timid approach can vitiate whatever protection the Congress has created for the consumer. On the other hand, an overly zealous approach can ruin a drug manufacturer by destroying public confidence in its products. Thus, it is understandable that the agency might have legitimate concern for drug manufacturers who must comply with new statutory requirements, and surely the question of time necessary to adduce new evidence of efficacy is an important consideration in creating an administrative scheme for implementation of the statute.

However, the FDA must remember that it does not stand alone in this regard. At the very outset the Congress also was sensitive to this problem, and allowed a two-year grace period before the 1962 amendments were to become effective. When, as is the case here, the Congress has shown an awareness of a problem and has acted accordingly, it seems inappropriate for an agency to adopt procedures which extend the grace period far beyond that envisioned by the statute, and which effectively stay implementation of the Congressional mandate that drugs in the marketplace be both safe and effective.[20]

NRC report on over-the-counter drugs, specifically cold remedies, that was submitted to the FDA three years ago. The report indicates that many of the nation's leading cold medications lack substantial evidence of effectiveness and are subject to withdrawal. Washington Post, July 8, 1972, p. 2.

[20] The defendants cite *Pfizer, Inc.* v. *Richardson*, 434 F.2d 536 (CA2 1970) and *Pharmaceutical Manufacturers Assn.* v. *Richardson*, 318 F.Supp. 301 (D.Del. 1970) as "specifically approv[ing] the procedures adopted by the defendants for the implementation of the NAS-NRC Drug Efficacy Study," but their reliance on these cases is

Based upon the entire record in this case, the court concludes that there is no compelling reason why the remaining NAS-NRC reports should not be immediately released, that it would be an abuse of agency discretion to refuse to make such reports public, and that the court should set a deadline for the FDA to complete its evaluation of all drugs with regard to efficacy.

Accordingly, the plaintiffs' motion for summary judgment is granted, and the defendants' motion to dismiss and for summary judgment is denied.

Counsel are directed to present an appropriate order.

/s/ William B. Bryant
Judge

Dated: August 23, 1972

misplaced, since they deal with the validity of FDA regulations regarding the definition of "substantial evidence" and the right to a hearing prior to withdrawal of a drug. Neither case deals with the issues before this court.

APPENDIX B

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Civil Action No. 1847-70

[Filed Oct. 11, 1972—James F. Davey, Clerk]

AMERICAN PUBLIC HEALTH ASSOCIATION, et al.,
Plaintiffs,

v.

JOHN G. VENEMAN, et al.,
Defendants.

ORDER

Pursuant to this Court's Memorandum and Order entered August 23, 1972, it is hereby ordered that:

I. Defendants shall release and make available to the public immediately all reports of the National Academy of Sciences-National Research Council (NAS-NRC) relating to the effectiveness of drugs approved for marketing between 1938 and 1962, which have previously been received by the Food and Drug Administration and not heretofore released, and shall release all such reports received in the future immediately upon receipt.

II. Defendants shall proceed expeditiously, using available resources and personnel to the maximum extent feasible consistent with its other obligations under the law, to complete implementation of the drug effectiveness review with respect to human drugs as soon as possible.

III. Within 120 days from the date of this Order, defendants shall evaluate all NAS-NRC reports for drugs not previously evaluated, and publish in the Federal Register an evaluation of each product as "effective," or "less than effective." For purposes of setting implementation priorities, each "less than effective" drug shall

be further classified as "probably effective," "possibly effective," or "ineffective" for each of its multiple indications. For a drug with multiple indications, overall classification of the drug shall depend on the highest evaluation given to any one of its multiple indications. Defendants may defer such evaluation for a limited number of drugs where further clarification from the NAS-NRC is requested or where further consultation with outside experts is pursued; in these situations a report shall be filed with the court which shall be available for public inspection, and evaluation shall proceed as rapidly as is feasible.

IV. Defendants shall, beginning immediately, proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "ineffective," in accordance with the following procedures, priorities, and time limitations:

A. For each drug subject to paragraph III which is classified as "ineffective," a Notice of Opportunity for Hearing on a proposal to withdraw approval of the new drug application or form 5 for such drug shall be published in the Federal Register concurrently with the publication on that evaluation.

B. Within 60 days from the date of this Order, a Notice of Opportunity for Hearing shall be published for all drugs previously classified in an evaluation published in the Federal Register as "ineffective" but for which such a Notice has not yet been published, unless a review of new data or information results in reclassification of the drug. If the drug is reclassified, an appropriate notice shall be published in the Federal Register and implementation with respect to the drug shall be handled as set out below.

C. With respect to each drug previously classified as "ineffective" and for which a Notice of Opportunity for Hearing has already been published in the Federal Register, a final order shall be published in the Federal Register ruling on such Notice as follows:

(1) within 60 days from the date of this Order, where no request for hearing has been filed in response to the Notice of Opportunity for Hearing within the statutory time limit or where a request for hearing is supported by no data or information whatever; and

(2) within 150 days from the date of this Order, where a request for hearing supported by data and information has been filed in response to such proposal.

D. Within 12 months of this Order, for a drug determined to be "ineffective" and for which a Notice of Opportunity for Hearing has been published pursuant to paragraphs IV(A) and (B) of this Order, a final order shall be published in the Federal Register ruling upon such request for hearing.

E. Work on administrative hearings and on court actions with respect to withdrawal of new drug applications and form 5's for drugs classified as "ineffective" and removal of other marketed drugs covered by such applications and form 5's shall take precedence over work on drugs classified as "possibly" or "probably effective" or as "effective."

V. Defendants shall proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "possibly effective," in accordance with the following procedures, priorities, and time limitations:

A. Within 15 months of this Order a Notice of Opportunity for Hearing shall be published in the Federal Register.

B. Within 30 months of this Order a final order ruling on any request for hearing filed within the statutory time limit in response to a Notice under subparagraph A above shall be published in the Federal Register.

C. Work on administrative hearings and on court actions with respect to withdrawal of new drug applications and form 5's for drugs classified as "possibly effective" and removal of other marketed drugs covered by such applications and form 5's shall take precedence over work on drugs classified as "probably effective" or as "effective."

VI. Defendants shall proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "probably effective" in accordance with the following procedures, priorities, and time limitations:

A. Within 33 months of this Order a Notice of Opportunity for Hearing shall be published in the Federal Register.

B. Within 42 months of this Order a final order ruling on any request for hearing filed within the statutory time limit in response to a Notice under subparagraph A above shall be published in the Federal Register.

C. Work on administrative hearings and on court actions with respect to withdrawal of new drug applications and form 5's for drugs classified as "probably effective" and removal of other marketed drugs covered by such applications and form 5's shall take precedence over work on drugs classified as "effective."

VII. Defendants shall proceed to implementation of the drug effectiveness review with respect to human prescription drugs classified as "effective" but with one or more less than effective indications pursuant to 21 U.S.C. 355(e) in accordance with the following procedures, priorities, and time limitations:

A. Within 45 months of this Order and after a refusal to delete all less than effective indications a Notice of Opportunity for Hearing shall be published in the Federal Register.

B. Within 48 months of this Order a final order ruling on the request for hearing filed within the statutory time limit in response to a Notice under subparagraph A above shall be published in the Federal Register.

VIII. Defendants may implement the drug effectiveness review with respect to any specific "possibly effective" or "probably effective" or "ineffective" drug not in accordance with the priorities established in paragraphs IV-VII where public health considerations or administrative efficiency justify such action.

IX. An order to withdraw the drugs shall be issued concurrently with any denial of a request for a hearing made under paragraphs IV(C), IV(D), V(B) of this Order. Defendants may grant a stay of such order in appropriate cases.

X. Defendants shall not grant any extension of time for any request for a hearing or other response to a Notice of Opportunity for Hearing.

XI. Any Notice of Opportunity for Hearing shall permit any person with an interest in an identical, related or similar product which is covered by the new drug application or antibiotic monograph an opportunity to submit data and information on the effectiveness of

the drug and a statement why the new drug application or form 5 should not be withdrawn and/or why a hearing should be held to consider the matter.

XII. Defendants shall schedule and conduct administrative hearings, when required by 21 C.F.R. 130.14(B), as expeditiously as practicable.

XIII. Upon withdrawal of a new drug application of form 5, Defendants shall make a good faith effort to find all identical, related, or similar products which are covered by the new drug application or antibiotic monograph and shall proceed to remove them from marketing as expeditiously as possible.

XVI. A limited number of drugs may remain on the market pending completion of scientific studies to determine effectiveness where there is a compelling justification of the medical need for the drug. Such justification shall be made by Defendants in writing, shall be filed with the Court, and shall be available for public inspection.

XV. Over-the-counter human drugs which are the subject of NAS-NRC reports shall be reviewed and handled pursuant to the procedure established in the Federal Register of May 11, 1972 (37 F.R. 9464 et seq.).

XVI. This Order does not affect the interim labeling and advertising requirement imposed by the Food and Drug Administration in the Federal Register of June 8, 1971 (36 F.R. 11022) and February 12, 1972 (37 F.R. 3175).

XVII. Six months after the date of this Order, and every six months thereafter until completion of the implementation of the drug effectiveness review, a report on the actions implementing this Order shall be submitted to this Court and shall be available for public inspection.

Such reports shall include:

(1) Statistical data showing actions taken on
of the various categories of drugs during the prev
six months and the number of drugs in the va
stages of review;

(2) Statistical data on work yet to be accompli
in the drug effectiveness review according to the va
categories of drugs and the various stages of revie

(3) The number and kinds of personnel who
assigned to the drug effectiveness review at the
and the conclusion of the previous six months and
estimated time each category of personnel spent on
review during this period;

(4) The predicted number and kinds of perso
who will be assigned to the drug effectiveness re
during the next six months and the estimated time
category of personnel will spend on the review dur
this period;

(5) Detailed information concerning any failure
comply with this Order and the reasons for this fail
and

(6) Any problems anticipated for the next six mo
in complying with this Order and possible methods
overcoming these problems.

XVIII. The Court expressly retains jurisdiction o
this proceeding to amend or modify any provisions
this Order as may be required.

/s/ William B. Bryant
Judge

October 10, 1972
Date